Clinical trial identification: NCT02163694.

Editorial acknowledgement: Medical writing services, provided by Alan Saltzman of JK Associates, Inc., were funded by AbbVie.

Legal entity responsible for the study: AbbVie Inc.

Funding: AbbVie.

Disclosure: V. Dieras: Advisory/Consultancy: Roche/Genentech; Advisory/Consultancy: Novartis; Advisory/Consultancy: Lilly; Advisory/Consultancy: Pfizer; Advisory/Consultancy: AbbVie; Advisory/Consultancy: MSD; Advisory/Consultancy: Daiichi Sankyo; Advisory/Consultancy: Seattle Genetics; Advisory/Consultancy: AstraZeneca. B. Arun: Leadership role, Research grant/Funding (institution), Steering committee (non-paid): AbbVie; Research grant/Funding (institution): PharmaMar; Research grant/Funding (institution): AstraZeneca; Research grant/Funding (institution): Invitae. H.S. Han: Research grant/Funding (institution): AbbVie; Research grant/Funding (institution): Prescient; Research grant/Funding (institution): Horizon; Research grant/Funding (institution): Karyopharm; Research grant/Funding (institution): BMS; Research grant/Funding (institution): Novartis; Research grant/Funding (institution): Pfizer; Research grant/Funding (institution): Tesaro; Research grant/Funding (institution): TapImmune; Research grant/Funding (institution): Seattle Genetics; Research grant/Funding (institution): Department of Defense; Speaker Bureau/Expert testimony: Lilly. H. Wildiers: Honoraria (institution), Advisory/Consultancy, Research grant/Funding (institution), Travel/Accommodation/Expenses: Roche; Honoraria (institution), Advisory/Consultancy: AstraZeneca; Honoraria (institution), Advisory/Consultancy: Lilly; Honoraria (institution), Advisory/Consultancy: Novartis; Honoraria (institution), Advisory/Consultancy: AbbVie; Honoraria (institution), Advisory/Consultancy: Vifor Pharma; Honoraria (institution), Advisory/Consultancy, Travel/Accommodation/Expenses: Pfizer; Honoraria (institution), Advisory/Consultancy: Celldex Therapeutics; Honoraria (institution), Advisory/Consultancy: Janssen-Cilag; Honoraria (institution), Advisory/Consultancy: TRM Oncology; Honoraria (institution), Advisory/Consultancy: PUMA Biotechnology; Honoraria (institution), Advisory/Consultancy: Amgen; Honoraria (institution), Advisory/Consultancy: Orion Corporation. M. Friedlander: Honoraria (self), Advisory/Consultancy, Speaker Bureau/Expert testimony, Research grant/Funding (self), Travel/Accommodation/Expenses: AstraZeneca; Honoraria (self), Advisory/Consultancy, Leadership role, Steering committee (remunerated): MSD; Advisory/Consultancy, Leadership role, Steering committee (non-remunerated): AbbVie; Honoraria (self), Advisory/Consultancy: Lilly; Honoraria (self), Advisory/Consultancy: Takeda; Honoraria (self), Advisory/Consultancy: Novartis; Research grant/Funding (institution): BeiGene. J.P. Ayoub: Research grant/Funding (institution): AbbVie; Research grant/Funding (institution): Boston Biomedical; Advisory/Consultancy: AstraZeneca; Advisory/Consultancy: Eisai; Advisory/Consultancy: Eli Lilly; Advisory/Consultancy: Novartis; Advisory/Consultancy, Speaker Bureau/Expert testimony: Pfizer; Advisory/Consultancy: Puma; Advisory/Consultancy: Roche. S. Puhalla: Advisory/Consultancy, Research grant/Funding (institution): AbbVie; Advisory/Consultancy: MedImmune; Advisory/Consultancy: Celldex; Advisory/Consultancy: Puma; Advisory/Consultancy, Research grant/Funding (institution): Pfizer; Advisory/Consultancy, Research grant/Funding (institution): AstraZeneca; Advisory/Consultancy: Eisai; Advisory/Consultancy: NanoString; Research grant/Funding (institution): Lilly; Research grant/Funding (institution): Novartis; Research grant/Funding (institution): Incyte; Research grant/Funding (institution): Covance-Bayer; Research grant/Funding (institution): Genentech; Research grant/Funding (institution): Medivation. S. Hudgens: Full/Part-time employment: Clinical Outcomes Solutions. L. Floden: Full/Part-time employment: Clinical Outcomes Solutions. N. Khandelwal: Shareholder/Stockholder/Stock options, Full/Part-time employment: AbbVie. K. Benjamin: Shareholder/Stockholder/Stock options, Full/Part-time employment: AbbVie. R. Kamalakar: Shareholder/Stockholder/Stock options, Full/Part-time employment: AbbVie. D. Maag: Shareholder/Stockholder/Stock options, Full/Part-time employment: AbbVie.

https://doi.org/10.1016/j.annonc.2020.08.376

2750 Impact of tucatinib on health-related quality of life (HRQoL) in patients with HER2+ metastatic breast cancer (MBC) with and without brain metastases (BM)

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Background: Patients (pts) with human epidermal growth factor receptor 2 positive (HER2+) MBC, particularly pts with BM, have limited treatment (tx) options and increased likelihood to report deterioration in HRQoL. Maintaining QoL in pts with MBC who progress through different lines of therapy is an important outcome in clinical trials. In the HER2CLIMB (H2C) study, tucatinib (TUC) + trastuzumab (T) + capecitabine (C) demonstrated statistically significant improvement in progression free survival (PFS) and overall survival (OS) over T + C alone. In HER2+ MBC pts with and without BM, TUC + T + C had a manageable safety profile similar to T + C alone. Here we report the impact of TUC on HRQoL, a secondary objective in H2C.

Methods: Assessment of HRQoL was initiated with protocol version 7, using the EQ-5D-5L which includes a EQ visual analog scale (EQ-VAS) and descriptive system (EQ-5D) of 5 health dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has 5 levels: no, slight, moderate, severe, or extreme problems. Data were available from 330 of 612 pts and were collected at Cycles (C) 1, 3-9 (every 2 C; 21 day C), C 12 and beyond (every 3 C), and at 30 day follow-up. TUC and placebo group EQ-5D-5L scores were calculated for each dimension and summarized. HRQoL pt reported outcomes were evaluated using longitudinal and descriptive data analyses.

Results: In H2C, data from 217 pts on the TUC arm and 113 pts on the placebo arm were available for HRQoL analyses. In all 5 EQ-5D-5L domains, most pts in both arms reported only slight or no problems. Reported moderate, severe, or extreme problems were low and similar between tx arms. No clinically meaningful differences in HRQoL were observed between tx arms. Mean EQ-5D-5L VAS scores were similar between tx arms and stable throughout duration of therapy. Decline on EQ-5D-5L domains and VAS scores were not seen while pts were on therapy. All available QoL data will be presented.

Conclusions: In H2C, addition of TUC resulted in statistically significant and clinically meaningful improvement in PFS and OS. Moreover, QoL in pts treated with TUC + T + C was maintained throughout the tx period which was longer compared to pts receiving only T + C.

Clinical trial identification: NCT02614794.

Editorial acknowledgement: Medical writing assistance was funded by Seattle Genetics, Inc., and provided by Aulma Parker, PhD, of Seattle Genetics, Inc.

Legal entity responsible for the study: Seattle Genetics.

Funding: Seattle Genetics.

Disclosure: V. Mueller: Honoraria (institution), Advisory/Consultancy: Amgen; Honoraria (institution): AstraZeneca; Honoraria (institution), Advisory/Consultancy, Travel/Accommodation/Expenses: Daiichi Sankyo; Honoraria (institution), Advisory/Consultancy: Eisai; Honoraria (institution): Genomic Health; Honoraria (institution), Advisory/Consultancy: Lilly; Honoraria (institution): MSD Oncology; Honoraria (institution), Advisory/Consultancy: Nektar; Honoraria (institution), Research grant/Funding (institution): Novartis; Honoraria (institution): Pierre Fabre; Honoraria (institution), Advisory/Consultancy, Travel/Accommodation/Expenses: Roche; Honoraria (institution), Advisory/Consultancy, Research grant/Funding (institution): Seattle Genetics; Honoraria (institution): Tesaro; Honoraria (institution): Teva; Advisory/Consultancy: Hexal; Research grant/Funding (institution): Roche/Genentech; Travel/Accommodation/Expenses: Pfizer. E. 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Hamilton: Research grant/Funding (institution): AbbVie; Research grant/Funding (institution): AceraPharma; Research grant/Funding (institution): Aravive; Research grant/Funding (institution): ArQule; Research grant/Funding (institution), Travel/Accommodation/Expenses: Arvinas; Advisory/Consultancy, Research grant/Funding (institution), Advisory/Consultancy paid to institution only: AstraZeneca; Research grant/Funding (institution): BerGenBio; Advisory/Consultancy, Research grant/Funding (institution), Advisory/Consultancy paid to institution only: Black Diamond Therapeutics; Advisory/Consultancy, Research grant/Funding (institution), Advisory/Consultancy paid to institution only: Boehringer Ingelheim; Research grant/Funding (institution): Clovis Oncology; Research grant/Funding (institution): Compugen; Research grant/Funding (institution): Curis; Research grant/Funding (institution): CytomX Therapeutics; Advisory/Consultancy, Research grant/Funding (institution), Advisory/Consultancy paid to institution only: Daiichi Sankyo; Research grant/Funding (institution): Deciphera; Research grant/Funding (institution): eFFECTOR Therapeutics; Research grant/Funding (institution), Travel/Accommodation/Expenses: Eisai; Research grant/Funding (institution), Travel/Accommodation/Expenses: EMD Serono; Research grant/Funding (institution): Fochon Pharma; Research grant/Funding (institution): Fosun Orinove; Research grant/Funding (institution): Fujifilm; Research grant/Funding (institution): G1 Therapeutics; Advisory/Consultancy, Research grant/Funding (institution), Travel/Accommodation/Expenses, Advisory/Consultancy paid to institution only: Genentech/Roche; Research grant/Funding (institution): H3 Biomedicine; Research grant/Funding (institution): Harpoon; Research grant/Funding (institution): Hutchison MediPharma; Research grant/Funding (institution): Immunigenics; Research grant/Funding (institution): InventisBio; Research grant/Funding (institution): Karyopharm Therapeutics; Research grant/Funding (institution): Leap Therapeutics; Advisory/Consultancy, Research grant/Funding (institution), Travel/Accommodation/Expenses, Advisory/Consultancy paid to institution only: Lilly; Research grant/Funding (institution): Lycera; Research grant/Funding (institution): Macrogenics; Research grant/Funding (institution): MedImmune; Research grant/Funding (institution): Mediation; Research grant/Funding (institution), Advisory/Consultancy paid to institution only: Mersana; Research grant/Funding (institution): Merus; Research grant/Funding (institution): Millennium; Research grant/Funding (institution): Molecular Templates; Advisory/Consultancy, Research grant/Funding (institution), Travel/Accommodation/Expenses, Advisory/Consultancy paid to institution only: Novartis; Research grant/Funding (institution): Nucana; Shareholder/Stockholder/Stock options: OncoMed; Research grant/Funding (institution), Travel/Accommodation/Expenses, Advisory/Consultancy paid to institution only: Pfizer; Advisory/Consultancy, Research grant/Funding (institution), Advisory/Consultancy paid to institution only: PumaBiotech; Research grant/Funding (institution): Radius Health; Research grant/Funding (institution): Regeneron; Research grant/Funding (institution): Rgenix; Research grant/Funding (institution): Seattle Genetics; Research grant/Funding (institution): Sermonix Pharma; Advisory/Consultancy, Research grant/Funding (institution), Advisory/Consultancy paid to institution only: Silverback Therapeutics; Research grant/Funding (institution): Stem CentRx; Research grant/Funding (institution): Sutro Biopharma; Research grant/Funding (institution): Syndax; Research grant/Funding (institution): Syrol Pharma; Research grant/Funding (institution): Taiho Pharma; Research grant/Funding (institution): Takeda; Research grant/Funding (institution), Travel/Accommodation/Expenses: Tesaro; Research grant/Funding (institution): Unum Therapeutics; Research grant/Funding (institution): Verastem; Research grant/

Funding (institution): Zenith Epigenetics; Research grant/Funding (institution): Zymeworks; Travel/Accommodation/Expenses: Amgen; Travel/Accommodation/Expenses: Bayer; Travel/Accommodation/Expenses: Bristol-Myers Squibb; Travel/Accommodation/Expenses: Clovis Oncology; Travel/Accommodation/Expenses: Foundation Medicine; Travel/Accommodation/Expenses: Genzyme; Travel/Accommodation/Expenses: Guardant Health; Travel/Accommodation/Expenses: Helsinn Therapeutics; Travel/Accommodation/Expenses: Heron; Travel/Accommodation/Expenses: Medivation; Travel/Accommodation/Expenses: Merck; Travel/Accommodation/Expenses: Sysmex. A. Zelnak: Advisory/Consultancy: Novartis; Advisory/Consultancy: Pfizer; Travel/Accommodation/Expenses: Immunomedics. E.H. Jakobsen: Advisory/Consultancy: Novartis; Advisory/Consultancy: Pfizer; Advisory/Consultancy: Roche; Advisory/Consultancy: Lilly. F. Boyle: Honoraria (self), Advisory/Consultancy: Roche; Honoraria (self), Advisory/Consultancy: Eli Lilly; Honoraria (self), Advisory/Consultancy: Pfizer; Honoraria (self), Advisory/Consultancy, Travel/Accommodation/Expenses: Novartis. E.H. Brix: Travel/Accommodation/Expenses: Roche; Travel/Accommodation/Expenses: Pfizer; Travel/Accommodation/Expenses: Pierre Fabre. A.J. Brenner: Advisory/Consultancy, Leadership role, Shareholder/Stockholder/Stock options, intellectual property interest: NanoTX; Advisory/Consultancy, Shareholder/Stockholder/Stock options: Plus Therapeutics; Honoraria (self), Advisory/Consultancy, Research grant/Funding (self), Travel/Accommodation/Expenses: Vascular Biogenics; Advisory/Consultancy: Alamab Therapeutics; Research grant/Funding (self): Threshold Pharmaceuticals; Research grant/Funding (institution): miRNA Therapeutics; Research grant/Funding (institution): Boston Biomedical; Research grant/Funding (institution): Upshaw Smith; Research grant/Funding (institution): Immunomedics; Research grant/Funding (institution): Medicenna. T. Arkenau: Full/Part-time employment: HCAHealthcare UK; Full/Part-time employment: Sarah Cannon; Advisory/Consultancy: Roche; Advisory/Consultancy: Beigene; Advisory/Consultancy: Bicycle; Advisory/Consultancy: iOnctura; Advisory/Consultancy: Bayer; Advisory/Consultancy: Servier; Advisory/Consultancy: Biontech. K.A. Gelmon: Advisory/Consultancy, Research grant/Funding (institution): AstraZeneca; Advisory/Consultancy, Research grant/Funding (institution): Bristol-Myers Squibb; Advisory/Consultancy: Genentech; Advisory/Consultancy: Genomic Health; Advisory/Consultancy: Janssen Oncology; Advisory/Consultancy: Lilly; Advisory/Consultancy: Merck; Advisory/Consultancy: Mylan; Advisory/Consultancy: NanoString Technologies; Advisory/Consultancy: Novartis; Advisory/Consultancy, Research grant/Funding (institution): Pfizer; Advisory/Consultancy, Research grant/Funding (institution): Roche. D. Cameron: Advisory/Consultancy, Research grant/Funding (institution): GlaxoSmithKlein; Advisory/Consultancy, Research grant/Funding (institution): Novartis; Advisory/Consultancy, Research grant/Funding (institution): Roche; Advisory/Consultancy: Synthon; Research grant/Funding (institution): Seattle Genetics; Full/Part-time employment: Edinburgh Cancer Research Centre; Full/Part-time employment: Edinburgh UK. G. Curigliano: Advisory/Consultancy: Bristol-Myers Squibb; Advisory/Consultancy, Speaker Bureau/Expert testimony: Lilly; Advisory/Consultancy: Novartis; Advisory/Consultancy, Speaker Bureau/Expert testimony: Pfizer; Advisory/Consultancy, Speaker Bureau/Expert testimony: Roche; Advisory/Consultancy, Speaker Bureau/Expert testimony, Research grant/Funding (institution): Seattle Genetics; Research grant/Funding (institution): Ellipsis; Full/Part-time employment: University of Milano, Istituto Europeo di Oncologia, IRCCS, Milan, Italy. K. DeBusk: Shareholder/Stockholder/Stock options, Full/Part-time employment: Seattle Genetics; Shareholder/Stockholder/Stock options: Roche. J. Ramos: Shareholder/Stockholder/Stock options, Full/Part-time employment: Seattle Genetics. X. An: Shareholder/Stockholder/Stock options, Full/Part-time employment: Seattle Genetics; Full/Part-time employment: Novartis. A.M. Wardley: Honoraria (self), Honoraria (institution), Advisory/Consultancy, Speaker Bureau/Expert testimony, Research grant/Funding (institution), Travel/Accommodation/Expenses: Roche; Honoraria (self), Honoraria (institution), Advisory/Consultancy, Speaker Bureau/Expert testimony, Research grant/Funding (institution): Novartis; Honoraria (self), Advisory/Consultancy, Speaker Bureau/Expert testimony, Research grant/Funding (institution): Pfizer; Honoraria (self), Advisory/Consultancy, Research grant/Funding (institution), Travel/Accommodation/Expenses: Daiichi Sankyo; Honoraria (self), Honoraria (institution), Advisory/Consultancy, Speaker Bureau/Expert testimony, Research grant/Funding (institution): Eli Lilly; Honoraria (self), Advisory/Consultancy, Research grant/Funding (institution), Travel/Accommodation/Expenses: MSD; Honoraria (self), Advisory/Consultancy, Research grant/Funding (institution): Athenex; Honoraria (self), Honoraria (institution), Advisory/Consultancy, Speaker Bureau/Expert testimony, Research grant/Funding (institution): AstraZeneca; Honoraria (self), Advisory/Consultancy: Gerson Lehrman Group; Honoraria (self), Advisory/Consultancy: Guidepoint Global; Honoraria (self): Coleman Expert Network; Honoraria (self): Helios; Honoraria (self): Health Care America; Advisory/Consultancy, Research grant/Funding (institution): Accord Research; Advisory/Consultancy: NAPP Pharma; Speaker Bureau/Expert testimony: Eisai; Leadership role, Research grant/Funding (self): NIHR Manchester Clinical Research Facility at The Christie Strategy Director for Association of Cancer Physicians ; Leadership role: Committee Member UK Breast Cancer Group; Leadership role: Committee Member NHS England Chemotherapy Clinical Reference Group; Leadership role: ESMO Breast cancer faculty; Research grant/Funding (institution): Seattle Genetics; Research grant/Funding (institution): IGI Therapeutics; Shareholder/Stockholder/Stock options, Officer/Board of Directors, Spouse/Financial dependant: Andrew Wardley Limited; Shareholder/Stockholder/Stock options, Officer/Board of Directors: Manchester Cancer Academy; Shareholder/Stockholder/Stock options, Officer/Board of Directors: Outreach Research & Innovation Group Limited; Full/Part-time employment: NIHR Manchester Clinical Research Facility at The Christie; Advisory/Consultancy: Coleman Research. All other authors have declared no conflicts of interest.

https://doi.org/10.1016/j.annonc.2020.08.377

276O Pooled analysis of patient (pt)-reported quality of life (QOL) in the MONALEESA (ML)-2, -3, and -7 trials of ribociclib (RIB) plus endocrine therapy (ET) to treat hormone receptor−positive, HER2-negative (HR+/HER2−) advanced breast cancer (ABC)

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Background: Pt-reported QOL results have been presented separately for each phase III ML trial, which tested efficacy and safety of RIB with different ET combination partners as first- or second-line treatment for HR+/HER2− ABC. Pooling the ML trial data enables a robust analysis of QOL that includes pre- and postmenopausal pts receiving different ET combination partners.

Methods: Health-related QOL and pain were evaluated using EORTC QLQ-C30 questionnaires. QOL was assessed for all pts in ML-2, pts receiving treatment as initial ET for ML-3, and pts receiving RIB or placebo (PBO) plus a nonsteroidal aromatase inhibitor as ET for ML-7. A linear effects model was used to determine least squares (LS) mean change from baseline (BL) in pain and global health status (GHS).

Results: QOL was assessed in 1528 pts from the ML trials. Time to definitive deterioration (TTDD) $\geq$ 10% for GHS, pain, and emotional functioning was delayed with RIB. Median TTDD $\geq$ 10% for GHS was 39.6 mo for RIB and 33.1 mo for PBO (hazard ratio [HR], 0.79 [95% CI, 0.66-0.94]). Median TTDD $\geq$ 10% for pain was not reached for RIB or PBO (HR, 0.77 [95% CI, 0.61-0.97]). Median TTDD $\geq$ 10% for emotional functioning was 46.9 mo for RIB and 35.9 mo for PBO (HR, 0.71 [95% CI, 0.59-0.85]). HRs for TTDD $\geq$ 10% for social and physical functioning and fatigue favored RIB but had wide 95% CIs (will be reported in detail at the congress). GHS/QOL was maintained from BL during treatment, but decreased at end of treatment (EOT) in both arms (LS mean change from BL at cycle 3 and EOT for RIB vs. PBO: +2.9 vs. +4.8 points and −3.7 vs. −2.7 points, respectively). Pain was improved from BL to cycle 3, maintained throughout treatment, and worsened at EOT (LS mean change from BL at cycle 3 and EOT for RIB vs. PBO: −4.3 vs. −3.2 points and +1.0 vs. +1.6 points, respectively).

Conclusions: In pts receiving first-line ET across the ML trials, RIB delayed deterioration in QOL. TTDD for GHS, pain, and emotional functioning scores was longer with RIB vs. PBO. Overall, this large, robust analysis demonstrated favorable QOL results with the addition of RIB to ET in patients with HR+/HER2− ABC.

Clinical trial identification: NCT01958021 (May 12, 2017); NCT02422615 (September 19, 2018); NCT02278120 (February 26, 2019).

Editorial acknowledgement: Medical writing support was provided by Casey Nielsen, PhD, at MediTech Media, Ltd, funded by Novartis Pharmaceuticals Corporation.

Legal entity responsible for the study: Novartis Pharmaceuticals Corporation.

Funding: Novartis Pharmaceuticals Corporation.

Disclosure: P.A. Fasching: Honoraria (self), Advisory/Consultancy, Research grant/Funding (institution), Advisory/Steering Board, Research Support: Novartis; Research grant/Funding (institution), Research Support: BionTech; Honoraria (self), Advisory/Consultancy, Advisory Board: Roche; Honoraria (self), Advisory/Consultancy, Advisory Board: Pfizer; Honoraria (self), Advisory/Consultancy, Advisory Board: Celgene; Honoraria (self), Lectures: Daiichi Sankyo; Honoraria (self), Advisory/Consultancy, Advisory Board, Lectures: Merck Sharpe and Dohme; Honoraria (self), Advisory/Consultancy, Advisory Board: Macrogenics; Honoraria (self), Advisory/Consultancy, Advisory Board: Eisai; Honoraria (self), Advisory/Consultancy, Advisory Board: Puma; Research grant/Funding (institution), Research Support: Cepheid; Honoraria (self), Advisory/Consultancy, Advisory Board, Lectures: Lilly; Honoraria (self), Advisory/Consultancy, Advisory Board: AstraZeneca. A. Bardia: Honoraria (self), Advisory/Consultancy, Research grant/Funding (institution), Travel/Accommodation/Expenses, Research Grant; Advisory Board; Consultancy; Travel Support: Genentech; Honoraria (self), Advisory/Consultancy, Research grant/Funding (institution), Travel/Accommodation/Expenses, Research Grant; Advisory Board; Consultancy; Travel Support: Novartis; Honoraria (self), Advisory/Consultancy, Research grant/Funding (institution), Travel/Accommodation/Expenses, Research Grant; Advisory Board; Consultancy; Travel Support: Pfizer; Honoraria (self), Advisory/Consultancy, Research grant/Funding (institution), Travel/Accommodation/Expenses, Research Grant; Advisory Board; Consultancy; Travel Support: Merck; Honoraria (self), Advisory/Consultancy, Research grant/Funding (institution), Travel/Accommodation/Expenses, Research Grant; Advisory Board; Consultancy; Travel Support: Sanofi; Honoraria (self), Advisory/Consultancy, Research grant/Funding (institution), Travel/Accommodation/Expenses, Research Grant; Advisory Board; Consultancy; Travel Support: Radius Health; Honoraria (self), Advisory/Consultancy, Research grant/Funding (institution), Travel/Accommodation/Expenses, Research Grant; Advisory Board; Consultancy; Travel Support: Immunomedics; Research grant/Funding (institution), Research Grant: Mersana; Research grant/Funding (institution), Research Grant: Innocrin; Advisory/Consultancy, Research grant/Funding (institution), Research Grant; Advisory Board: Biothernostics Inc.; Honoraria (self), Advisory/Consultancy, Travel/Accommodation/Expenses, Advisory Board; Consultancy; Travel Support: Spectrum Pharma;